

data and information in the environmental document to the extent possible.

[50 FR 16656, Apr. 26, 1985, as amended at 61 FR 14245, Apr. 1, 1996]

§ 25.31 Environmental assessment formats.

(a) As defined by CEQ in 40 CFR 1508.9, the EA is the public document in which environmental and other pertinent information on a proposed action are presented, providing a basis for the agency's determination whether to prepare an EIS or a FONSI.

(b) An EA shall be prepared in the format presented in this section for each action not categorically excluded in § 25.24. The EA shall be a complete, objective, and well-balanced document that allows the public to understand the agency's decision.

(c) Consistent with 40 CFR 1500.4(j) and 1502.21, EA's may incorporate by reference information presented in other documents that are available to FDA and to the public.

§ 25.31a Environmental assessment for proposed approvals of FDA-regulated products—Format 1.

(a) For proposed actions to approve food or color additives, drugs, biological products, animal drugs, and class III medical devices, for proposed actions to affirm food substances as generally recognized as safe (GRAS), and for proposed actions to grant requests for exemption from regulation as a food additive, the applicant or petitioner shall prepare an environmental assessment in the following format:

ENVIRONMENTAL ASSESSMENT

1. *Date:*
2. *Name of applicant/petitioner:*
3. *Address:*
4. *Description of the proposed action:* Briefly describe the requested approval; need for the action; the locations where the products will be produced; to the extent possible, the locations where the products will be used and disposed of; and the types of environments present at and adjacent to those locations.
5. *Identification of chemical substances that are the subject of the proposed action:* Provide complete nomenclature, CAS Reg. No. (if available), molecular weight, structural formulae, physical description, additives, and impurities. This information is required to be adequate to allow accurate location of

data about chemicals in the scientific literature and to allow identification of closely related chemicals.

6. *Introduction of substances into the environment:* For the site(s) of production: list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval of the proposed action will have upon compliance with current emissions requirements at the production site(s). Through use of calculations and/or direct measures, estimate to the extent possible the quantities and concentrations of substances expected to enter the environment as a result of use and/or disposal of products affected by the action.

7. *Fate of emitted substances in the environment:* Predict environmental concentrations of and exposures to substances entering the environment as a consequence (direct or indirect) of the use and/or disposal of the products affected by the action for the following environmental compartments, including consideration of the major environmental transport and transformation processes involved:

(a) Air—taking into account, to the extent possible, factors such as volatilization, photochemical and chemical degradation, rainout, and dispersion;

(b) Freshwater, estuarine, and marine ecosystems—taking into account, to the extent possible, factors such as chemical and biological degradation, exchange between the water column and sediments via sorption/desorption and biological processes, accumulation in animals, plants, and other organisms, introductions due to rainfall and losses due to volatilization;

(c) Terrestrial ecosystems—taking into account, to the extent possible, factors such as chemical and biological degradation, sorption/desorption and leaching in soils, accumulation in animals and plants, introductions due to rainfall, losses due to volatilization, and entry into groundwater.

8. *Environmental effects of released substances:* Given the information developed on the introduction (item 6) and fate (item 7) of substances which would be released as a consequence of the use and/or disposal of the products affected by the action, use any relevant toxicological data or other appropriate measures to predict, to the extent applicable, effects on animals, plants, humans, other organisms, and effects at the ecosystem-level in each of the environmental compartments listed in item 7.

9. *Use of resources and energy:* Specify the natural resources, including land use, minerals, and energy, required to produce, transport, use, and/or dispose of a given amount of any product which is the subject of the action, including the resources and energy required to dispose of wastes generated from